DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 3,2014

Sterilucent, Inc
% Peter Kalkbrenner
Director of Engineering
1400 Marshall Street Ne
Minneapolis, Minnesota 55413

Re: K141412
Trade/Device Name: Sterilucent Self-Seal Sterilization Pouch
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: October 31, 2014
Received: November 5, 2014

Dear Peter Kalkbrenner,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141412

Device Name
Sterilucent Self-Seal Sterilization Pouch

Indications for Use *(Describe)*
The Sterilucent Self-Seal Sterilization Pouch is intended to be used to enclose medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The pouches are intended to be used in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen Cycles.

Pouch Models and Sizes

Catalog No.	Size
SL264	3.5” x 9”
SL265	4” x 22”
SL266	5.25” x 10”
SL267	5” x 15”
SL268	7.5” x 13”
SL269	12” x 15”
SL270	12” x 18”

The PSD-85 Lumen Cycle has been validated to sterilize a load of up to ten (10) pounds (combined pouch and wrapped tray load) containing a maximum of ten (10) single channel stainless steel lumens per load with the following dimensions:

- An inside diameter of 1 mm or larger and a length of 60 mm or shorter;
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter;
- An inside diameter of 3 mm or larger and a length of 350 mm or shorter.

The PSD-85 Non-Lumen Cycle has been validated to sterilize a load of up to 25 pounds (combined pouch and wrapped tray load).
The maximum validated pouch load is two (2) pounds.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
for the
Sterilucent Self-Seal Sterilization Pouch
K141412

Owner:	GS Medical Packaging, Inc.
Address:	501 Lakeshore Road East Suite 201A Mississauga, ON L5G 1H9 Canada
Telephone:	905-271-1523
Fax:	905-271-1526

Contact:	Peter Kalkbrenner Director of Engineering Sterilucent, Inc. 1400 Marshall St. NE Minneapolis, MN 55413
Telephone:	612-767-3253
Fax:	612-767-3260

Summary Date:	25 November, 2014

1. Device Name and Classification

Trade Name:	Sterilucent Self-Seal Sterilization Pouch
Common/Usual Name:	Sterilization Pouch
Classification Name:	Sterilization Wrap, Containers, Trays, Cassettes & Other Accessories
Product Code:	FRG (21 CFR 880.6850)
Class:	II

2. Predicate Device

Steris Vis-U-All Self Seal Pouch (K070765)

3. Device Description

The Sterilucent Self-Seal Sterilization Pouch is a self sealing pouch used to enclose another medical device that is to be sterilized by a healthcare provider. It is available in sizes to suit the healthcare provider. Devices are inserted into the pouch, sealed, and then sterilized in the Sterilucent low temperature vaporized hydrogen peroxide (VHP) process. After completion of the sterilization process, the pouch maintains sterility of the enclosed medical devices until the seal is opened.

The pouches are constructed of a Tyvek backing with a clear, laminated polyethylene terephthalate (PET)/low density polyethylene (LDPE) film material front. The self-seal pouch permits sealing of the pouch without need of heat-sealing equipment.

4. Statement of Intended Use:

The Sterilucent Self-Seal Sterilization Pouch is intended to be used to enclose medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The pouches are intended to be used in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen Cycles.

Pouch Models and Sizes

Catalog No.	Size
SL264	3.5” x 9”
SL265	4” x 22”
SL266	5.25” x 10”
SL267	5” x 15”

SL268	7.5” x 13”
SL269	12” x 15”
SL270	12” x 18”

The PSD-85 Lumen Cycle has been validated to sterilize a load of up to ten (10) pounds (combined pouch and wrapped tray load) containing a maximum of ten (10) single channel stainless steel lumens per load with the following dimensions:

- An inside diameter of 1 mm or larger and a length of 60 mm or shorter;
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter;
- An inside diameter of 3 mm or larger and a length of 350 mm or shorter.

The PSD-85 Non-Lumen Cycle has been validated to sterilize a load of up to 25 pounds (combined pouch and wrapped tray load).
The maximum validated pouch load is two (2) pounds.

5. Technological Characteristics Summary Comparison

The Sterilucent Self-Seal Sterilization Pouch has similar technological characteristics as the predicate device:

Summary of Technological Characteristics of the Device Compared to the Predicate Device		
Characteristic	**New Device**	**Predicate Device**
Indications for Use	The Sterilucent Self-Seal Sterilization Pouch is intended to be used to enclose medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The pouches are intended to be used in Sterilucent vaporized hydrogen peroxide (VHP) sterilization processes	The Vis-U-All Self Seal Pouch is a sterilization containment pouch designed for devices to be sterilized by the health care provider by the AMSCO V-PRO 1 Low Temperature Sterilization System. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
Materials	Clear laminated PET/LDPE film (front) and Tyvek® (back)	Same
Construction	Front and back materials are sealed on three (3) sides. Fourth side (end) remains open for filling. End is sealed by removing protective liner strip, folding along the pre-fold, and pressing to the film.	Same
Sterilization Modality	Low temperature vaporized hydrogen peroxide	Same
Process Indicator	None (requires external ISO 11140, Class 1 process indicator)	ISO 11140, Class 1
Presentation	Clean peel chevron seal on one end for aseptic presentation	Same

6. Summary of Non-Clinical Performance Data

Sterilization performance studies were conducted for the Sterilucent Self-Seal Sterilization Pouch and all acceptance criteria were met. Sterilization efficacy testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of 10^{-6} using the biological (BI) overkill method and half-cycle validation under worst case conditions. Real time event related shelf life studies demonstrated sterility maintenance for a 180 day time period. Whole package microbial challenge testing, exposing pouches to a minimum of 1×10^6 *Bacillus atrophaeus* colony forming units (CFU) via an aerosol challenge, demonstrated appropriate microbial barrier properties following exposure to the Sterilucent hydrogen peroxide sterilization processes under worst case conditions.

7. Summary of Clinical Performance Data

N/A – No clinical tests were conducted for this submission.

8. Overall Performance Conclusion Statement

The non-clinical studies demonstrated that the Sterilucent Self-Seal Sterilization Pouch is substantially equivalence to the predicate device.